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FM AMEMBASSY WARSAW  
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RUCPDOC/DEPT OF COMMERCE WASHINGTON DC  
RUEATRS/DEPT OF TREASURY WASHDC

C O N F I D E N T I A L SECTION 01 OF 03 WARSAW 000594

SIPDIS

STATE PASS TO USTR FOR WMOORE

E.O. 12958: DECL: 05/12/2018

TAGS: ECON ETRD KIPR PL

SUBJECT: PHARMACEUTICALS: NEW REIMBURSEMENT LIST LEAVES COMPANIES WANTING MORE

REF: A. 07 WARSAW 2212

¶B. WARSAW 99

Classified By: Economic Counselor Richard Rorvig for reasons:  
1.4(b and d)

¶1. (C) Summary: On May 14, Polish Health Minister Ewa Kopacz announced a draft update to the list of drugs eligible for reimbursement from the National Health Fund. As expected, the list contains only generics. The new list is sure to raise the frustration level of U.S. producers of innovative pharmaceuticals. Nevertheless, most of those companies expect excellent results this year from sales of drugs added to the reimbursement list in November 2007. End summary.

¶2. (U) The updated list still needs to go through "internal consultations" within the Polish government before it becomes final, but that is a ministerial process unlikely to result in any changes. The update added 17 generics, in 23 formulations, to the reimbursement list, and extended coverage for treatment of three chronic diseases. The prices of 85 drugs on the list were lowered, and the Ministry struck 140 drugs off the list. Minister Kopacz stated these were primarily drugs that are no longer produced, or that had been withdrawn from the market.

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How November 2007 List is Perceived  
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¶3. (C) Post and U.S. innovative pharmaceuticals companies operating in Poland regarded the previous update to the reimbursement list, on November 2, 2007, as a major breakthrough (ref A). However, that view is not universal. The former PiS-led government issued the list as one of its last acts. At the time, some contacts speculated that PiS had approved several very expensive drugs in the hopes that, if the cost proved unmanageable, PO would be blamed for either mismanaging the health budget or reducing access to medicines.

¶4. (SBU) Shortly after the November list was published, media reported that a drug made by a French company had been added to the list at the last minute, after a private dinner between that company's representatives and former PiS Vice Minister of Health, Boleslaw Piecha. Subsequently, it was asserted that the French company's drug had been on the list, and then dropped through back-room machinations of a Polish company that makes a competing product and wanted to stifle competition. Piecha asserted that the French company's drug was simply restored to the list, after having been improperly removed. Whatever the truth, the incident gave rise to the perception that the November 2007 list was tainted by

corruption.

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Anti-Corruption Efforts and the Health Ministry  
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¶ 15. (C) PO came into government determined to stifle the perceived corruption. In every meeting Embassy officials have had with senior Health Ministry officials, they have stressed their determination to handle matters differently than their predecessors. Under new rules, all meetings with Ministry officials must be requested in writing, and the meetings are both tape recorded and attended by two witnesses from the Ministry's Office of Legal Counsel. This makes for jarring atmospherics. Ministry officials give off a palpable sense of paranoia that any contact with persons from outside the Ministry may expose them to accusations of corruption. Pharmaceuticals companies complain it has become nearly impossible to consult with Ministry officials over the telephone, and claim that routine access to the Ministry has been substantially restricted.

¶ 16. (C) However, the Ministry now posts on its website a list of all meetings between Ministry officials and private companies. The list shows that from March 6 to March 31 the Ministry met 16 times with companies or industry groups, including INFARMA, Eli Lilly, AstraZeneca, GlaxoSmithKline, Pfizer and Janssen Cilag. General managers (GMs) of Glaxo and Eli Lilly told EconOff that, in the six months PO has been in office, they have met with the Ministry twice. A Pfizer official stated most of their contact recently has been with the Health Technology Assessment unit (HTA). Clearly companies find the new requirements noisome, and the

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tape recording and witnesses doubtless make for a strange and stiff atmosphere, but companies are, in fact, able to meet with Ministry officials.

¶ 17. (C) Because the PO officials put in place what they regard as a transparent system under which any company can meet with Ministry officials, at first they did not see the benefit of continuing regular group meetings with the Pharmaceuticals Committee of the AmCham, known as "LAWG." However, they have now come around. Following a push from Washington officials in the recent U.S.-Poland Economic-Commercial Dialogue, Vice Minister Marek Twardowski met with LAWG members on April 22, and committed to continuing the dialogue. On May 5, Minister Kopacz reiterated to the Ambassador her willingness to continue the Ministry-LAWG meetings.

¶ 18. (C) Although the Ministry-LAWG dialogue is back on track, U.S. innovative pharmaceuticals companies are still struggling to build a real partnership with the PO government. LAWG organized a campaign, called "Let's Vote for Health," aimed at raising public awareness of the value of innovation in health care. They convoked a high-level study group, which prepared a synthesis of prior studies and a list of reform recommendations. The next step is to "socialize" the recommendations with government decision-makers, but so far the group has been struggling to interest officials in the effort.

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Ministry Worries About Paying for the List  
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¶ 19. (C) Ref B reported companies' estimates that the November 2007 additions to the reimbursement list would mean at least US\$120 million in increased revenues for them. While good news for the companies, the Ministry continues to worry about how to pay for those drugs, let alone further additions to the list. Minister Kopacz told the Ambassador that the cost of reimbursed drugs accounts for 1/6th of the National Health Service budget. In his meeting with the LAWG

members, Vice Minister Twardowski stated price is the main issue holding up adding more drugs to the list. Going forward, the Ministry is considering using as a guideline the World Health Organization's standard for measuring a drug's cost effectiveness. This states that interventions for which the additional cost incurred to gain one quality-adjusted life year is less than the country's per capita GDP (in Poland's case, about US\$15,000) are deemed "very cost-effective," those between one and three times per capita GDP "cost-effective," and those with an additional cost of over three times per capita GDP "cost-ineffective." At a subsequent LAWG meeting, a Pfizer representative told EconOff that, for innovative pharmaceuticals, she believed setting the "cost-effective" bar at four, five or six times GDP per capita would be more appropriate. She added that the Ministry is too focused on figuring out what it can afford, rather than how to meet Poland's health care needs, stating, "They have a budget, not priorities."

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When Will the Process Get Better?  
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¶10. (C) Artur Falek, Director of the Department responsible for updates to the reimbursement list, also attended Twardowski's meeting with LAWG. He stated that some innovative pharmaceuticals might be added to the list in June, if the HTA is able to finish its review of the drugs in time. Eli Lilly's GM told EconOff he believes the HTA is grossly exceeding its mandate. Glaxo's GM stated that the HTA's role should be limited to assessing a drug's safety and efficacy, and that -- given the HTA's new role as a gatekeeper to the reimbursement list -- he fears it will become the next focus of corruption. The GM of Bristol Myers Squibb (BMS) told EconOff that, based on his contacts with the Ministry regarding BMS' pending dossiers, he does not believe the Ministry could possibly have another update to the reimbursement list ready by June. He anticipated that, in the whole of 2008, five to ten innovative drugs might be added to the list.

¶11. (C) The pharmaceutical companies' most significant complaint continues to be lack of clear criteria for determining which drugs get added to the list. For example, it is unclear why schizophrenia treatments were added to the list in November 2007, but treatments for other diseases were

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passed over. A "twinning" project with France, designed to increase transparency, just concluded. Falek stated that the Ministry is completing a draft of a new transparency law, and plans to push for the legislation to be enacted by year-end. Vice Minister Twardowski stated that he hopes to eliminate the backlog of applications to the reimbursement list by the end of 2008.

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Keeping Complaints in Perspective  
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¶12. (C) Pharmaceutical company officials remain skeptical. As one GM stated, "the mood music is very pleasant," but he sees "no meaningful progress toward a transparent system." This grumbling needs to be kept in perspective. Those companies that had drugs added to the November 2007 list report they are hiring new employees, and expect to post strong results this year. Tellingly, the number of companies participating in LAWG meetings, as well as the level of representation, has dropped off markedly. A year ago the LAWG meetings were packed with frustrated GMs. In contrast, only two people -- the GM running the meeting and a low level employee of another company -- bothered to show up at the planning session for the LAWG-Twardowski meeting. After the LAWG-Twardowski meeting, one GM noted that LAWG could sue the Polish government for failing to meet the requirement in Polish law to update the reimbursement list quarterly.

Another GM, one of the Ministry's loudest critics, immediately replied that his company "would never sue a customer," but that the companies should continue trying to increase the pressure applied to Poland by Washington and Brussels.

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Comment  
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¶13. (C) Post expects continued progress on pharmaceuticals, but also expects progress to continue to come in fits and starts. The Health Ministry is most focused on containing costs, and it now seems clear that the PO government probably will not be much better than its predecessors at updating the reimbursement list on time. Minister Kopacz told the Ambassador that she understands the importance of intellectual property rights, and that her Ministry's contact with the USG should not be limited to concerns about the reimbursement list. She plans to send a proposal to broaden USG cooperation with the Health Ministry, and is especially keen to learn about U.S. experience with transplants and diagnosing special risks.

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